



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Patent term



NOV 12 1998

Food and Drug Administration
Rockville MD 20857

#21

Re: Tasmar®
Docket No.: 98E-0480

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

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Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,236,952, filed by Hoffman-La Roche, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Tasmar®, the human drug product claimed by the patent.

The total length of the regulatory review period for Tasmar® is 2,618 days. Of this time, 2,014 days occurred during the testing phase and 604 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 1, 1990.

The applicant claims November 28, 1990, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 1, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 5, 1996.

The applicant claims June 3, 1996, as the date the New Drug Application (NDA) for Tasmar® (NDA 20-697) was initially submitted. However, FDA records indicate that NDA 20-697 was submitted on June 5, 1996.

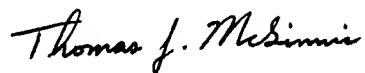
3. The date the application was approved: January 29, 1998.

FDA has verified the applicant's claim that NDA 20-697 was approved on January 29, 1998.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "Thomas J. McGinnis".

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: George Johnston
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley, NJ 07110